DEC 0 6 2006
PATENT AND TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Application No. | : | 10/765,926 | Confirmation No.: 2903 |
| Applicant | : | Baldomero M. OLIVERA et al. | |
| Filed | : | 29 January 2004 | |
| TC/A.U. | : | 1653 | |
| Examiner | : | Shawn A. HAMIDINIA | |
| Attorney Docket No. | : | 2314-273 | |
| Customer No. | : | 6449 | |

Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

Dear Sir:

In the Office Action mailed 6 June 2006, the Examiner required restriction between three Groups. In response thereto, Applicants herewith elect Group I. This election is made without traverse.

In addition to the restriction to the three Groups, the Examiner also required restriction to a single peptide. In response thereto, Applicants herewith elect the peptide w-GVIA having SEQ ID NO:143. Claims 1, 2 and 5 read on this election. This election is made with traverse to the extent that examination would not include the propeptide (SEQ ID NO:142) of this mature peptide.

Specifically, there are two criteria for a proper requirement for restriction between patentably distinct inventions: 1) The inventions must be independent or distinct as claimed; and 2) There must be a serious burden on the Examiner if restriction is not required. See MPEP § 803. Examiners must provide reasons and/or examples to support conclusions. For purposes of the initial requirement, a serious burden on the Examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to

Markush-type claims is concerned, the criteria are set forth in MPEP § 803.02. See MPEP § 803. If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not require restriction. See MPEP § 803.02.

Applicants agree that the peptide and the propeptide may be distinct from each other. However, as stated in the MPEP, as discussed above, distinctness alone is not enough to require a restriction. There must also be a serious burden upon the Examiner. In the absence of such a burden, the Examiner must examine all of the claims (or in this case, it is urged that the peptide and propeptide claims should be examined). It is urged that the burden of examining the peptide and propeptide claims of the present application is not a serious one, and that the burden of examining the peptide and propeptide claims is only slightly greater than examining one alone.

The examination entails various aspects. First is a decision concerning utility under 35 U.S.C. §101. Although each peptide species being claimed is distinct, they are related in that one is a propeptide of the other. Consequently, a decision concerning utility will be identical for all of the species, and there is no added burden of examining all of the species (i.e., mature peptide and propeptide) as compared to examining only a single species (i.e., mature peptide).

The second aspect of examination is whether the provisions of the various paragraphs of 35 U.S.C. § 112 have been met. In general, and in this case, this means reviewing the application and claims for compliance with the provisions of paragraphs 1 and 2 of § 112. As for the enablement aspect as found in paragraph 1 of § 112, all of the peptides are related in their structure and biological activity. Since no basis for distinguishing between the enablement of one species vs. another species has been set forth, it is presumed that all of the listed peptides will be treated equally. Again, this means that only a single decision needs to be made concerning all of the peptides. Therefore, this aspect of the examination will not be a serious burden if all peptides are examined, vs. only one of the peptides.

Concerning paragraph 2 of § 112, this involves the wording of the claims. The wording of the claims in each group of claims is identical except for the specified peptide. Consequently, any objections to the language of the claims for one Group of claims is equally applicable to the other Groups of claims. Therefore there is no increase in the burden concerning 35 U.S.C. § 112, second paragraph, if all peptide claims are examined.

The third aspect of examination is a review of prior art to determine whether the claims are anticipated or obvious. There are two aspects of such a search. A first aspect is a review of the prior art literature and patents. The literature to be reviewed will be identical for all of the peptides. All of the claimed peptides have similar, though not identical, structures. The Examiner has not stated that a search of the scientific literature will be any different for one peptide than for any other peptide. Consequently, the search of the patent literature will clearly be the same for all of the peptides. Because the search of the scientific literature and patent literature will be identical for all of the peptides, there is no added burden concerning this aspect if all of the peptides are examined. Furthermore, the search will probably entail a computer search based on the peptide sequences in the sequence listing. It is believed that such a search would identify prior art directed to the claimed peptides or peptides having the specified substitutions. For example, Applicants submit that a search of the peptide will also identify its propeptide, thus there is no additional burden in searching the propeptide.

Consequently, it is submitted that the only reason for restriction is that the peptides are distinct from each other. But as explicitly stated in MPEP § 803, the inventions must be distinct and there must be a serious burden on the examiner. MPEP § 803.02 states that if a search and examination of an entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. As urged above, it is asserted that examination of all of the peptides claims will not impose a serious burden.

In addition, it is submitted that the computer search for the mature toxin will also identify and prior art disclosing the propeptide and will identify prior art disclosing derivatives of the mature

toxin. Consequently no additional searching is required to examine the propeptide and derivatives with the corresponding mature toxins, and thus no undue burden exists in this instance.

In view of the above arguments, it is requested that the restriction requirement imposed in the Office Action mailed 6 June 2006 be reconsidered in the event that the Examiner intended to restrict the propeptide from the peptide and that both of these peptides be examined together.

Respectfully submitted,

ROTHWELL, FIGG, ERNST & MANBECK, p.c.

By _____

Jeffrey L. Ihnen, Reg. No. 28,957
Attorney for Applicants
1425 K Street, N.W., Suite 800
Washington, D.C. 20005
Telephone No.: (202) 783-6040
Facsimile No.: (202) 783-6031

#1367326v1<RFDMS> -2314-273.Response Restriction